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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,686	12/10/2003	Yaron Ilan	59046.000043	9035

21967 7590 09/21/2009

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
09/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,686	ILAN ET AL.	
	Examiner	Art Unit	
	EMILY M. LE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/17/08 and 05/07/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,40-42,45-49,63 and 64* is/are pending in the application.

4a) Of the above claim(s) *46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37, 40-42, 45, 47-49 and 63-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/07/2009 has been entered.

Status of Claims

2. Claims 1-36, 38-39, 43-44 and 50-62 are cancelled. Claims 37, 40-42, 45-49 and 63-64 are pending. Claim 46 is withdrawn from consideration because it is not drawn to the elected invention, which is HCV. Claims 37, 40-42, 45, 47-49 and 63-64 are under examination.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 4-6, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa et al.,[1] in view of Motoki et al.,[2] in further view of Lin et al.[3]

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[1] Ogawa et al. U.S. Patent No. 5861520, published January 19, 1999.

The claims are directed to a process comprising the active step of a) obtaining cells from a subject, b) treating said cells with an intermediary metabolite or a reagent that increases the intracellular level of a mammalian intermediary metabolite in said cells, and c) transferring said treated cells to said subject to a virally infected subject. Claim 40, which depends on claim 37, requires the glycolipid to comprise a monosaccharide ceramide, which is limited to glucosyl ceramide and galactosyl ceramide by claim 41. Claim 42, which depends on claim 37, requires the transferring step be carried by intravenous means. Claim 45, which depends on claim 37, requires the viral infection be HCV. Claim 47, which depends on claim 37, requires the reagent to increase the rate of production of said glycolipid in said subject. Claim 48, which depends on claim 37, requires the reagent to decrease the rate of degradation or turnover of said glycolipid in said subject. Claim 49, which depends on claim 37, requires the cells obtained from said subject to comprise peripheral blood monocytes (PBMCs), dendritic cells, T cells, stem cells, NK cells, NKT cells and CD1d cells. Claims 63-64, which depend on claims 40-41, respectively, require the viral infection to be HCV.

Motoki et al. teaches of glycolipids. The glycolipids of Motoki et al. are monosaccharide ceramide, including beta-glucosylceramide and beta-galactosylceramide. Motoki et al. teaches the administration, subcutaneous, of beta-glucosylceramide and beta-galactosylceramide to a subject.

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[2] Motoki et al. Immunostimulatory and antitumor activities of monoglycosylceramides having various sugar moieties. Biol. Pharm. Bull., November 1995, Vol. 18, No. 11, 1487-1491.
[3] Lin et al. U.S. Patent No. 6043339, published March 28, 2000.

The subject of Motoki et al. is not a virally infected subject, including humans. However, at the time the invention was made, Ogawa et al. also teaches that glycolipids, including beta anomers of the glucosylceramide and galactosylceramides closely relates to receptor functions for physiologically active substances and important cell functions, such as generation, proliferation, differentiation or immune reactions, via intercellular recognition and interactions. Ogawa et al. also establishes that it is known that glycolipids play a role as a receptor in the host side in the infection with bacteria and viruses. [Lines 55-61, column 1, in particular.]Based on this knowledge, Ogawa et al. discloses the use of glycolipids to inhibit viral infections. Thus, at the time the invention was made, Ogawa et al. establishes that glycolipids have antiviral activities.

Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to administer the glycolipids taught by Motoki et al. to a virally infected subject, including human and those infected with HBV, HCV or HIV. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to inhibit viral infection or to induce an immune response against the infection. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the antiviral activities of glycolipids has been demonstrated and established by Ogawa et al.

Neither Ogawa et al. nor Motoki et al. teach an ex vivo method of administration of the glycolipid. However, at the time the invention was made, Lin et al. teaches a process comprising the active step of a) obtaining cells from a subject, b) treating said cells with reagent, and c) transferring, intravenously said treated cells to said subject.

Lin et al. also notes that the process can be used to deliver glycolipids. [Lines 37-46, column 2, in particular.] Thus, at the time the invention was made, it would have been prima facie obvious for one of ordinary skill in the art to administer the glycolipid of Motoki et al. using the process of Lin et al. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to import facilitate delivery/administration of glycolipids to a subject. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because Lin et al. teaches that glycolipids can be administered using the administration process disclosed by Lin et al.

Conclusion

5. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMILY M. LE whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EMILY M LE/
Primary Examiner, Art Unit 1648

/E. M. L./
Primary Examiner, Art Unit 1648